defendants Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known as Ortho-McNeil-

DRINKER BIDDLE & REATH LLP 50 Fremont Street, 20th Floor San Francisco, CA 94105

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KER BIDDLE & ŘEATH LLP 50 Fremont Street, 20th Floor n Francisco, CA 94105

Janssen Pharmaceuticals, Inc. ("OMJPI"), and McKesson Corporation ("McKesson") is
this action. I make this Declaration based on my personal knowledge, in support of the
removal by OMP, now known as OMJPI, of Kathleen Anderson, et al. v. Ortho-McNei
Pharmaceutical, Inc., McKesson Corp., and Does 1-500, inclusive, Case Number CGC
07-467829 to this Court. I would and could competently testify to the matters stated in
this Declaration if called as a witness.

- A true and accurate copy of the Complaint (the "Complaint") in this action 2. is attached as Exhibit A. The Complaint is the only state court pleading known to OMP, now known as OMJPI, and to McKesson to have been filed in this action.
- OMP was a corporation existing under the laws of the State of Delaware, with its principal place of business in New Jersey, and is now known as OMJPI, which is a Pennsylvania corporation, with its principal place of business also in New Jersey. OMP, now known as OMJPI, was served with the Summons and First Amended Complaint in this action on January 29, 2008.
- McKesson was served with the Summons and Complaint in this action on 4. January 30, 2008. McKesson consents to removal of this action to this Court.
- OMP, now known as OMJPI, will file a notice of the filing of this Notice of Removal and Removal in the San Francisco County Superior Court and will serve plaintiffs' counsel with a copy.
- 6. On March 1, 2006, the Judicial Panel on Multidistrict Litigation ("JPML") created MDL 1742, In re: Ortho Evra Products Liability Litigation, ruling that all federal actions involving allegations of injury or death from use of the prescription drug Ortho Evra® be centralized for pre-trial purposes in the United States District Court for the Northern District of Ohio, before the Honorable David A. Katz, Case Number 1:06-CV-40000-DAK. To date, over 900 cases have been transferred to MDL 1742, and transfers of additional "tag-along" actions are pending.
- Attached as Exhibit B is a true and accurate copy of the Declaration of Greg Yonko, Senior Vice President - Purchasing, McKesson Corporation, filed in Abel,

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Theresa, et al. v. Ortho-McNeil Pharmaceutical, Inc., et al., United States District Cour
Northern District of California, Case No. C 06 7551 SBA, on December 8, 2006.

- Attached as Exhibit C is a true and accurate copy of the Slip Opinion 8. denying the plaintiffs' motion to remand in Barlow, et al. v. Warner-Lambert Co., et al., Case No. CV 03-1647-R(RZx), in the United States District Court for the Central District of California (Western Division), dated April 28, 2003.
- 9. Attached as Exhibit D is a true and accurate copy of the Slip Opinion denying the plaintiffs' motion to remand in Skinner, et al. v. Warner-Lambert Co., et al., Case No. CV 03-1643-R(RZx), in the United States District Court for the Central District of California (Western Division), dated April 28, 2003.
- 10. I have reviewed reports of verdicts and settlements in cases in this judicial district, brought by plaintiffs claiming serious injuries from the use of prescription drugs or medical devices. Given the similarity between the injuries alleged in those cases and plaintiffs' claims, it is reasonably believed that if plaintiffs succeeded in proving their allegations in this action, they would each recover in excess of \$75,000, exclusive of interest and costs. Plaintiffs claiming substantially similar injuries in the Ortho Evra® MDL have specifically alleged that the amount in controversy in their respective actions exceeds \$75,000, exclusive of interest and costs.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on February  $\lambda$ , 2008.

**EXHIBIT A** 

Document 2-2

Filed 02/08/2008 29 Page 2 of 24

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT: (AVISO AL DEMANDADO):

ORTHO-MCNEIL PHARMACEUTICAL, INC., a Delaware Corporation, MCKESSON CORP, and DOES 1-500, inclusive

YOU ARE BEING SUED BY PLAINTIFF: (LO ESTÁ DEMANDANDO EL DEMANDANTE):
KATHLEEN ANDERSON, an individual, MARY RUTH BAYGENTS, an individual, LATOYA DUNLAP, an individual,

FOR COURT USE ONLY (SOLO PARA USO DE LA CORTE

Additional Parties Attachment form is attached.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the court house lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney right away. If you do not know an attorney, you may want to call an program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpealifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que processen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de Galifornia (www.courtinfo.ca.gov/selfhelp/espanol/), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no presenta una respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que l'ame a un abogado inmediatamente. Si no conoce a un abogado, puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sítio web de (www.courtinfo.ca.gov/selfhelp/espanol/) o poniéndose en contacto con la corte o el colegio de abogados locales.

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Sonia Tandon (Bar # 23	19614)	demandante que no tiene abogado, es):
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Form Adopted for Mandalogy Use Judicial Council of California SUM-100 (Rev. January 1, 2004)

Page 1 of 1

other (specify): by personal delivery on (date):

SHORT TITLE: KATHLEEN ANDERSON v. ORTHO-MCNEIL PHARMACEUTICAL, INC. et al.	CASE NUMBER: CGC-07-467829
INSTRUCTIONS FOR USE  This form may be used as an attachment to any summons if space does not permit  If this attachment is used, insert the following statement in the plaintiff or defendant Attachment form is attached."	the listing of all parties on the summons. box on the summons: "Additional Parties
List additional parties (Check only one box. Use a separate page for each type of party):	
X Plaintiff Defendant Cross-Complainant Cross-Defe	indant
JANE ENGLAND, an individual, ANQUARLA HADLEY, an individual, Individual, MELISSA ISON, an individual, DOLORES KITCHCART, an individual, SHERKIA MELLERSON, an individual, CHERI THORNHILL TRUSLOW, an individual	RHONDAGAIL HOWARD, an

Page \_2 of 2

Page 4 of 24 Case 3:08-cv-00862-SC Document 2-2 Filed 02/08/2008 ENDORGED SHAWN KHORRAMI, ESQ., SBN 180411 DYLAN POLLARD, ESQ., SBN 180306 SONIA TANDON, ESQ., SBN 239614 KHORRAMI, POLLARD & ABIR, LLP OCT 0 8 2007 2 CONDON PARKAL, Cler 444 S. Flower Street 3 JUNE PROPER Thirty-Third Floor Los Angeles, CA 90071 Telephone: (213) 596-6000 Facsimile: (213) 596-6010 email: skhorrami@kpalawyers.com 6 CASEMANAGEMENT CONFERENCE SET BRIAN KABATECK, ESQ., SBN 152054 RICHARD KELLNER, ESQ., SBN 171416 KABATECK BROWN KELLNER LLP MAR 0 7 2008 -9 MAM 8 644 South Figueroa Street Los Angeles, CA 90071 Telephone: (213) 217-5000 Facsimile: (213) 217-5010 DEPARTMENT 212 email: bsk@kbklawyers.com 10 MICHAEL S. BURG, ESQ. 11 SETH A. KATZ, ESQ. JANET G. ABARAY, ESQ. 12 BURG SIMPSON ELDREDGE HERSH JARDINE PC 13 40 Inverness Drive East Denver, CO 80112 Telephone: (303) 792-5595 14 Facsimile: (303) 708-0527 15 Attorneys for Plaintiffs 16 17 SUPERIOR COURT OF THE STATE OF CALIFORNIA 18 COUNTY OF SAN FRANCISCO 19 KATHLEEN ANDERSON, an individual; Case No. CGC-07-267829 MARY RUTH BAYGENTS, an individual; 20 LATOYA DUNLAP, an individual; JANE ENGLAND, an individual; ANQUARLA 21 COMPLAINT FOR DAMAGES BASED HADLEY, an individual; RHONDAGAIL HOWARD, an individual; MELISSA ISON, an) 22 individual; DOLORES KITCHCART, an individual; JUNE MCKENZIE, an individual; 23 I. NEGLIGENCE SHERKIA MELLERSON, an individual; STRICT PRODUCT LIABILITY -2. CHERI THORNHILL, an individual; 24 FAILURE TO WARN KATHRYN TRUSLOW, an individual, BREACH OF EXPRESS 3. 25 WARRANTY BREACH OF IMPLIED 4 Plaintiffs 26 WARRANTY 5. NEGLIGENT MISREPRESENTATION 27 6. FRAUD 28 DEMAND FOR JURY TRIAL

COMPLAINT FOR DAMAGES

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## JURISDICTION AND VENUE

- 5. The California Superior Court has jurisdiction over this action pursuant to California Constitution Article VI, Section 10, which grants the Superior Court "original jurisdiction in all causes except those given by statute to other trial courts." The Statutes under which this action is brought do not specify any other basis for jurisdiction.
- 6. The California Superior Court has jurisdiction over the Defendants because, based on information and belief, each is a corporation and/or entity and/or person organized under the laws of the State of California, a foreign corporation or association authorized to do business in California and registered with the California Secretary of State or has sufficient minimum contacts in California, is a citizen of California, or otherwise intentionally avails itself of the California market so as to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.
- 7. Venue is proper in this Court pursuant to California Code of Civil Procedure Section 395 in that Defendant MCKESSON has its principle place of business in San Francisco.
- 8. Furthermore Defendants ORTHO-MCNEIL and MCKESSON have purposefully availed themselves of the benefits and the protections of the laws within the State of California. Defendant MCKESSON has its principle place of business within the state. Defendants ORTHO-MCNEIL and MCKESSON have had sufficient contact such that the exercise of jurisdiction would be consistent with the traditional notions of fair play and substantial justice.
- 9. Plaintiffs each individually seek relief that is within the jurisdictional limits of the court.

## **PARTIES**

### **PLAINTIFFS**

- 10. Plaintiff KATHLEEN ANDERSON is a resident of Ottowa, Illinois, who was prescribed Ortho Evra and was severely injured as a result.
- 11. Plaintiff MARY RUTH BAYGENTS is a resident of Chicago, Illinois, who was prescribed Ortho Evra and was severely injured as a result.
  - 12. Plaintiff LATOYA DUNLAP is a resident of Abeline; Texas, who was prescribed

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Ortho Evra and was severely injured as a result.

- 13. Plaintiff JANE ENGLAND is a resident of Chester, Virginia, who was prescribed Ortho Evra and was severely injured as a result.
- 14. Plaintiff ANQUARLA HADLEY is a resident of Atlanta, Georgia, who was prescribed Ortho Evra and was severely injured as a result.
- 15. Plaintiff RHONDAGAIL HOWARD is a resident of Stamfort, Connecticut, who was prescribed Ortho Evra and was severely injured as a result.
- 16. Plaintiff MELISSA ISON is a resident of Huntington, West Virginia, who was prescribed Ortho Evra and was severely injured as a result.
- 17. Plaintiff DELORES KITCHCART is a resident of Elmira, New York, who was prescribed Ortho Evra and was severely injured as a result.
- 18. Plaintiff JUNE MCKENZIE is a resident of Chicago, Illinois, who was prescribed Ortho Evra and was severely injured as a result.
- 19. Plaintiff SHERKIA MELLERSON is a resident of Glen Burnie, Maryland, who was prescribed Ortho Evra and was severely injured as a result.
- 20. Plaintiff CHERI THORNHILL is a resident of Ocean Springs, Massachusetts, who was prescribed Ortho Evra and was severely injured as a result.
- 21. Plaintiff KATHRYN TRUSLOW is a resident of Kannapolis, North Carolina, who was prescribed Ortho Evra and was severely injured as a result.

## **DEFENDANTS**

- 22. Defendant ORTHO-MCNEIL is, and at all times material to this action was, a corporation organized, existing and doing business under and by the virtue of the laws of the State of Delaware, with its principle office located at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.
- 23. Defendant ORTHO-MCNEIL is, and at all times material to this action was, authorized to do business, and was engaged in business in the State of California. ORTHO-MCNEIL derives substantial revenue from goods consumed within the State of California.
  - 24. Defendant ORTHO-MCNEIL includes any and all parents, subsidiaries, affiliates,

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27 28 divisions, franchises, partners, joint venturers and organizational units of any kind, their predecessors, successors and assigns and their pr0esent officers, directors, employees, agents, representatives and other persons acting on their behalf.

- Plaintiffs are informed and believe, and based thereon allege, that in committing 25. the acts alleged herein, each and every managing agent, agent, representative and/or employee of the defendant was working within the course and scope of said agency, representation and/or employment with the knowledge, consent, ratification, and authorization of the Defendant and its directors, officers and/or managing agents.
- At all times material to this action, Defendant ORTHO-MCNEIL developed, 26. manufactured, marketed, promoted, sold and/or distributed Ortho Evra in the stream of commerce and in the State of California and the rest of the country.
- Defendant MCKESSON is, and at all times material to this action was, a 27. corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principle place of business in San Francisco, California. MCKESSON is, and at all times material to this action was, authorized to do business, and was engaged in substantial commerce and business under the laws of the State of California.
- Defendant MCKESSON includes any and all parents, subsidiaries, affiliates, 28. divisions, franchises, partners, joint venturers and organizational units of any kind, their predecessors, successors and assigns and their present officers, directors, employees, agents, representatives and other persons acting on their behalf.
- Plaintiffs are informed and believe, and based thereon allege, that in committing 29. the acts alleged herein, each and every managing agent, agent, representative and/or employee of Defendant MCKESSON was working within the course and scope of said agency, representation and/or employment with the knowledge, consent, ratification and authorization of the defendant and its directors, officers and/or managing agents.
- At all times relevant to this action, Defendant MCKESSON packaged, distributed, 30. supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or to inform users regarding the risks pertaining to, and

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assuaged concerns about the pharmaceutical Ortho Evra.

- The true names and capacities, whether individual, corporate, associate, or 31. otherwise, of Defendants named herein as DOES 1 through 500, and each of them, are unknown to Plaintiffs, who therefore, sues said Defendants by such fictitious names.
- Plaintiffs will ask leave to amend this Complaint to state said Defendants' true 32. identities and capacities when the same has been ascertained.
- Plaintiffs are informed and believe and based thereupon allege that each of the 33. Defendants designated herein as DOE took part in and participated with the Defendant in all matters referred to herein and was in some manner responsible for the injuries and losses suffered by the Plaintiffs.
- Plaintiffs are informed and believe and based thereupon allege that at all times 34. herein mentioned each of the Defendants was the agent, servant and/or employee or occupied other relationships with each of the other named Defendants and at all times herein mentioned acted within the course and scope of said agency and/or employment and/or other relationship and each other Defendant has ratified, consented to, and approved the acts of his agents, employees, and representatives, and that each actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

## TO ALL CAUSES OF ACTION

- ORTHO-MCNEIL is the world's leading manufacturer of prescription 35. contraceptives as well as the current market leader in oral and patch contraceptive products. ORTHO-MCNEIL offers a range of prescription birth control options to women, including Ortho Evra, the first transdermal contraceptive patch, ten birth control pills and two diaphragms.
- 36. The pharmaceutical drug at issue in this litigation is "Ortho Evra". Ortho Evra is the first and only once a week birth control patch. It is worn on the skin for one week and replaced on the same day of the week for three consecutive weeks, with the fourth week free from the patch. Unlike traditional oral contraceptives, such as the birth control pill, that are ingested and metabolized by the body's digestive system, the Ortho Evra patch continuously

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27 28 releases estrogen and progestin directly into the bloodstream.

- 37. ORTHO-MCNEIL filed a new drug application for Ortho Evra on or about December 21, 2000. In the same year, doctors at the FDA reviewing the clinical trials of the Ortho Evra patch warned that blood clots could be a problem if the patch were approved. This was after two of the women developed deep vein thrombosis (a blood clot that forms in the deep veins of leg or pelvic region) which led to pulmonary embolism (a serious and deadly condition of deep vein thrombosis where the clot breaks off into the lung and clogs an artery). One medical reviewer wrote that it would be important to study users after Ortho Evra came into the market for clot problems.
- 38. Despite those concerns, Ortho Evra received FDA approval for the prevention of pregnancy in November of 2001. Since then, Ortho Evra has been prescribed to more than 4 million women and has become one of the fastest growing birth control method in the United States.
- Since its approval the there have been many reports that indicate the serious risks associated with the consumption of Ortho Evra. In particular, the FDA has logged 9,116 reports of adverse reactions to the patch in a 17 month period. This is significantly higher than 1,237 adverse reports generated in a 6 year period for ORTHO-MCNEIL's oral contraceptive, Ortho Tri-Cyclen. According to the FDA, this only represents 1% - 10% of patch related medical problems so these adverse reactions are actually more prevalent.
- 40. Furthermore, reports provided by the FDA indicate that the risk of developing and/or dying from a blood clot while using the Ortho Evra patch is at least three times higher than when using birth control pills.
- On November 10, 2005, the FDA required that the warning label for Ortho Evra be updated to included a new warning indicating that use of Ortho Evra exposes women to a higher level of estrogen than use of other birth control methods. Specifically, the new bolded warning stated that women who use Ortho Evra are exposed to about 60% more total estrogen in their blood than if they were taking a typical birth control pill containing 35 micrograms of estrogen. Increased levels of estrogen exposes women to a greater risk of serious side effects,

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particularly blood clots in the legs and lungs, heart attacks and strokes.

- Ortho Evra was, and still continues to be, aggressively marketed as an easy to use, 42. safe, and effective alternative to oral contraceptives. Its main allure is in its convenience since Ortho Evra only needs to be applied once a week, unlike oral contraceptive that need to be taken daily to be effective.
- Defendant ORTHO-MCNEIL failed to appropriately warn Plaintiffs and 43. prescribing physicians of the serious risks of strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems.
- Despite the higher levels of estrogen that are known to be released by Ortho Evra 44. and the blood clot warnings, the package insert states that "there is limited epidemiological data available to determine whether safety with the transdermal route of administration is different than the oral route". The package insert goes on to say that "the information contained in this package insert is principally based on studies carried out in women who used combination oral contraceptives...".
- Defendant ORTHO-MCNEIL knew, or should have known, about the above .45. mentioned risks based upon the state of knowledge of ORTHO-MCNEIL as it existed at that time. Additionally, ORTHO-MCNEIL failed to properly or adequately investigate the safety concerns of Ortho Evra.
- Defendant ORTHO-MCNEIL's conduct fell below the duty of care that was 46. owed by Defendants to Plaintiffs.
- 47. Defendant ORTHO-MCNEIL misrepresented the known risks associated with the use of Ortho Evra. ORTHO-MCNEIL also made claims with regards to the safe and efficacious nature of their product in the prevention of pregnancy.
- Defendant ORTHO-MCNEIL negligently and recklessly failed to inform the 48. public, prescribing healthcare professionals and the FDA of the risks of strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems associated with use of their product, Ortho Evra.
  - 49. Defendant ORTHO-MCNEIL was careless and negligent in their manufacturing,

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testing, selling, distributing, merchandising, advertising, promoting, packaging, and marketing of Ortho Eyra.

By reason of the foregoing, Plaintiffs have suffered from strokes, pulmonary 50. emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems.

## FRAUDULENT CONCEALMENT

- Any applicable statute of limitations have been tolled by the knowing and active concealment and denial of facts as alleged herein by the Defendants. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not have reasonably discovered the dangerous nature and unreasonable adverse side effects associated with Ortho Evra. As a result, Plaintiffs did not discover the facts giving rise to these claims until less than one year before the filing of this Complaint.
- Defendants are and were under a continuing duty to disclose the true character, quality and nature of the patch to Plaintiffs. Because of their concealment of the true character, quality and nature of the contraceptive, Defendants are estopped from relying on any statute of limitations defense.

Negligence (Against Defendants ORTHO-MCNEIL and MCKESSON)

- Plaintiffs incorporate by reference the allegations in all preceding paragraphs of 53. this Complaint as though fully set forth in this paragraph.
- Defendants had a duty to exercise reasonable care in the manufacture, sale, 54. research, development, inspection, labeling, promoting, marketing, and/or distribution of Ortho Evra into the stream of commerce, including a duty to assure that this patch did not cause users to suffer from unreasonable, dangerous side effects.
- Defendants ORTHO-MCNEIL and MCKESSON failed to exercise ordinary care 55. in the manufacture, sale, testing, quality assurance, quality control, marketing and/or distribution of Ortho Evra into interstate commerce, in that Defendants knew or should have known that

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using Ortho Evra created a high risk of unreasonable dangerous side effects, including but not limited to the risk of strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems.

- Defendants ORTHO-MCNEIL and MCKESSON breached their duty to Plaintiffs 56. and were negligent in the licensing, testing, design, manufacture, packaging, warning, advertising, promotion, distribution, and sale of Ortho Evra in that Defendants:
  - Failed to use ordinary care in designing and manufacturing the Ortho Evra so as to avoid the aforementioned risks to Plaintiffs;
  - Failed to accompany Ortho Evra with proper warnings regarding the B. possible adverse side effects associated with the use of the patch and the comparative severity and duration of such adverse effects, i.e., the warnings given did not accurately reflect the symptoms, scope or severity of the side effects:
  - Failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety and side effects of Ortho Evra;
  - Failed to provide adequate training to medical care providers for D. appropriate use of Ortho Evra;
  - Failed to warn Plaintiffs, either directly or indirectly, orally or in writing, E. about the following:
    - The need for comprehensive, regular monitoring to ensure early (i) discovery of potentially serious side effects like blood clots, deep vein thrombosis and pulmonary emboli;
    - The possibility of becoming injured, disabled or dying as a result (ii) of using Ortho Evra.
  - Failed to adequately test and/or warn about the serious side effects of F. Ortho Evra;
  - Failed to include adequate warnings with Ortho Evra that would alert G. Plaintiffs, physicians, hospitals, and clinics, to the potential risks and the

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- nature, scope, severity, and duration of any serious side effects of Ortho Evra:
- H. Continued to promote the efficacy and safety of Ortho Evra while providing little or no warnings, and downplaying any risks, even after Defendants knew of the risks of serious injury and/or death;
- I. Delayed warnings of, and then failed to provide adequate warnings about the serious injuries, which may have dissuaded medical providers from prescribing Ortho Evra and deprived women of information so that they can weigh the true risks against the benefits of prescribing Ortho Evra; and
- Were otherwise careless or negligent. J.
- Despite the fact that Defendants knew or should have known that Ortho Evra 57. caused unreasonably dangerous side effects, Defendants continued and are currently continuing to market, manufacture, distribute and/or sell Ortho Evra to consumers, including Plaintiffs and their doctors.
- Defendants knew or should have known that consumers, such as Plaintiffs, would 58. suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
- Plaintiffs are entitled to punitive damages because the Defendants' failure to warn was reckless and without regard for the public's safety and welfare. The Defendants misled both the medical community and the public at large, including Plaintiffs, by making false representations about the safety of Ortho Evra. The Defendants downplayed, understated, and disregarded their knowledge of the serious side effects associated with the use of Ortho Evra despite available information demonstrating that their products were likely to cause serious and potentially fatal side effects to users like Plaintiffs.
- As a direct, proximate and legal result of the negligence, carelessness, other 60. wrongdoing and actions of the Defendants described herein, Plaintiffs were, and/or still are, caused to suffer severe injuries including diminished enjoyment of life, strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent

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health problems.

- Based upon information and belief, Defendants actually knew of Ortho Evra's 61. defective nature, as set forth herein, but continued, and still continue, to design, manufacture, market and sell the patch so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious disregard of the foreseeable harm caused by the patch.
- Defendants' conduct in the license, design, manufacturing, assembly, packaging, 62. warning, marketing, advertising, promotion, distribution and sale of Ortho Evra constituted malice, oppression and fraud, including, but not limited to:
  - Aggressively marketing and promoting Ortho Evra, knowing the high risks posed by failing to conduct sufficient pre-clinical and clinical testing and adequate post-marketing surveillance;
  - В. Failing to include adequate warnings with Ortho Evra that would alert consumers, physicians, hospitals, clinics, and other users to the potential risks and the nature, scope, severity, and duration of any serious side effects of the patch, particularly, strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems;
  - Continuing to promote the efficacy and safety of the patch, while C. providing little or no warnings, and downplaying any risks, even after Defendants knew of the increased risks associated with use of Ortho Evra as opposed to oral contraceptives;
  - Delaying warnings of the dangerous side effects which may have D. dissuaded medical providers from prescribing Ortho Evra so freely, and depriving women of information so that they could weigh the true risks against the benefits of using the patch, was fraudulent, knowing misconduct, and/or conduct undertaken recklessly and with conscious disregard for the safety of consumers such as the Plaintiffs, such as to

constitute despicable conduct, and oppression, fraud and malice, and such conduct was at all times relevant ratified by the corporate Defendants herein, thereby entitling Plaintiffs punitive damages in an amount appropriate to punish and set an example of Defendant.

63. As a result of ORTHO-MCNEIL and MCKESSON's conduct, Plaintiffs suffered injuries and damages herein.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as set forth herein below.

## SECOND CAUSE OF ACTION

Strict Product Liability - Failure to Warn (Against Defendants ORTHO-MCNEIL and MCKESSON)

- 64. Plaintiffs incorporate by reference the allegations in all proceeding paragraphs of this Complaint as though fully set forth in this paragraph.
- 65. Defendants ORTHO-MCNEIL and MCKESSON are the manufacturer and/or supplier of Ortho Evra.
- 66. Ortho Evra manufactured and/or supplied by Defendants ORTHO-MCNEIL and MCKESSON was unaccompanied by proper warnings regarding all possible side effects associated with their use and the comparative severity, incidence, and duration of such adverse effects, i.e., the warnings given did not accurately reflect the signs, symptoms, incidence, scope or severity of the side effects.
- 67. Defendants failed to perform adequate testing that would have shown that Ortho Evra possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made, both with respect to the use of the patch.
- 68. Ortho Evra manufactured and/or supplied by Defendants was defective due to inadequate post-marketing surveillance and/or warnings or instructions because, after the manufacturer knew or should have known of the risks of injury from Ortho Evra, they failed to provide adequate warnings to users or consumers of the patch and continued, and still continue, to aggressively promote Ortho Evra.

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- Ortho Evra manufactured and/or supplied by Defendants was defective because 69. Defendants were aware that the amount of estrogen that is released from the patch is much higher than the levels associated with oral contraceptives.
- 70. As a direct, proximate and legal result of the negligence, carelessness, other wrongdoing and actions of Defendants described herein, Plaintiffs have been injured as described above.
- Based upon information and belief, Defendants actually knew of the defective 71. nature of Ortho Evra, as set forth herein, but continued, and still continue, to design manufacture, market and sell Ortho Evra so as to maximize sales and profits at the expense of the health and safety of the public including Plaintiffs, in conscious disregard of the foreseeable harm caused by Ortho Evra.
- Plaintiffs could not, by reasonable exercise of care, have discovered the defects 72. and dangers of Ortho Evra.
- Defendants conduct in the license, design, manufacturing, assembly, packaging, warning, marketing, advertising, promotion, distribution, and sale of Ortho Evra constituted malice, oppression and fraud, including, but not limited to:
  - Aggressively marketing and promoting Ortho Evra, knowing the high A. risks posed by failing to conduct sufficient pre-clinical and clinical testing and adequate post-marketing surveillance;
  - Failing to provide complete literature with regards to Ortho Evra, and B. indicating the need for monitoring while on the patch;
  - Failing to include adequate warnings with Ortho Evra that would alert C. consumers, physicians, hospitals, clinics and other users to the potential risks and the nature, scope, severity, and duration of any serious side effects of the drug, particularly the risk of strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems;
  - Continuing to promote the efficacy and safety of the drug, while providing D.

little or no warnings, and downplaying any risks, even after Defendants knew of the increased risks associated with Ortho Evra use;

- E. Delaying warnings about the dangerous side effects which may have dissuaded medical providers from prescribing Ortho Evra so freely, and depriving women of information so that they could weigh the true risks against the benefits of using the patch, was fraudulent, knowing misconduct, and/or conduct undertaken recklessly and with conscious disregard for the safety of consumers such as the Plaintiffs, such as to constitute despicable conduct, fraud and malice, and such conduct was at all times relevant ratified by corporate Defendants herein, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish and set an example of Defendant.
- 74. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.
- 75. As a result of Defendants' conduct, Plaintiffs have sustained injuries described above.
- 76. Accordingly, Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as set forth herein below.

## THIRD CAUSE OF ACTION

(Against Defendants ORTHO-MCNEIL and MCKESSON)

- 77. Plaintiffs incorporate by reference the allegations in all preceding paragraphs of this Complaint as though fully set forth in this paragraph.
- 78. Defendants, ORTHO-MCNEIL and MCKESSON, through description, affirmation of fact, and promise relating to Ortho Evra, to the FDA, prescribing physicians, and the general public, including Plaintiffs, expressly warranted that Ortho Evra was safe and well accepted by users.

- 79. Defendants, ORTHO-MCNEIL and MCKESSON further expressly warranted that Ortho Evra did not produce any side effects in excess of those risks associated with oral contraceptives, that the side effects were reflected accurately in the warnings, and that it was accurately tested and fit for its intended use.
- 80. Ortho Evra does not conform to these express representations because it is not safe as its use produces serious adverse side effects including the risk of strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems.
- 81. As such, Defendants' product was neither in conformity to the promises, descriptions or affirmations of fact made about the patch nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.
- 82. Defendants knew or should have known that, in fact, said representations and warranties were false and misleading in that Ortho Evra was not safe and/or fit for its intended use, and in fact resulted in serious injuries to the user.
- 83. Plaintiffs relied on the express warranties of the Defendants herein. Members of the medical community, including physicians, and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Ortho Evra in prescribing, recommending, and/or dispensing the product.
- B4. Defendants thereafter breached their express warranties to Plaintiffs by: (i) manufacturing, marketing, packaging, labeling, and selling Ortho Evra to Plaintiffs in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Plaintiffs or their prescribing physicians or pharmacists, or without so modifying or excluding such express warranties; (ii) manufacturing, marketing, packaging, labeling, and selling Ortho Evra to Plaintiffs, which failed to prevent pregnancy in a safe manner and without injury; and (iii) manufacturing, marketing, packaging, labeling, and selling Ortho Evra to Plaintiffs, thereby causing injury to each.
- 85. As a direct and proximate result of Defendants' conduct the Plaintiffs were and still are caused to suffer severe injuries and physical pain including diminished enjoyment of

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27 28 life, strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems.

Plaintiffs are entitled to punitive damages because Defendants' failure to warn .86. was reckless and without regard to their welfare. Defendants misled both the medical community and the public at large, including Plaintiffs, by making false representations about the safety of their product. Defendants downplayed, understated, and disregarded their knowledge of the serious side effects associated with the use of Ortho Evra, despite available information demonstrating that it was likely to cause serious and sometimes fatal side effects to users.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as set forth herein below.

Breach of Implied Warranty (Against Defendants ORTHO-MCNEIL and MCKESSON)

- Plaintiffs incorporate by reference the allegations in all preceding paragraphs of 87. this Complaint as though fully set forth in this paragraph.
- At the time Defendants ORTHO-MCNEIL and MCKESSON marketed, sold, and 88. distributed Ortho Evra, for use by Plaintiffs, Defendants knew of the use for which Ortho Evra was intended and impliedly warranted the patch to be of merchantable quality and safe and fit for its intended use.
- Defendants ORTHO-MCNEIL and MCKESSON impliedly represented and 89. warranted to Plaintiffs, healthcare professionals and the FDA that the Ortha Evra it was supplying was safe and fit for ordinary use.
- Plaintiffs and members of the medical community relied on Defendants 90. warranties that their product, Ortho Evra, was of merchantable quality and safe and fit for its intended use.
- Contrary to such implied warranties, Ortho Evra was not of merchantable quality 91. or safe or fit for its intended use, because it was unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.
  - 92. Defendant's conduct in the license, design, manufacturing, assembly, packaging,

warning, marketing, advertising, promotion, distribution, and sale of Ortho Evra constituted malice, oppression and fraud, including but not limited to:

- A. Marketing and promoting the product aggressively, knowing the high risks posed by failing to conduct sufficient pre-clinical and clinical testing and adequate post-market surveillance;
- B. Failing to provide complete literature with regards to Ortho Evra and indicating the need for monitoring while on the patch;
- C. Failing to include adequate warnings with Ortho Evra that would alert consumers, physicians, hospitals, clinics and other users of the potential risks and the nature, scope, severity and duration of any serious side effects of the patch, particularly, the risks of strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems;
- D. Continuing to promote the efficacy and safety of Ortho Evra, while providing little or no warnings, and downplaying any risks, even after the Defendants knew of the increased risks associated with use of their product;
- E. Delaying warnings of, and then failing to provide adequate warnings about the dangerous side effects which may have dissuaded medical providers from prescribing Ortho Evra so freely, and depriving women of information so that they could weigh the true risks against the benefits of prescribing the product, was fraudulent, knowing misconduct, and/or conduct undertaken recklessly and with conscious disregard for the safety of consumers like Plaintiffs, such as to constitute despicable conduct, oppression, fraud and malice, and such conduct was at all times relevant ratified by the corporate Defendants herein, thereby entitling Plaintiffs punitive damages in an amount appropriate to punish and set an example of the Defendants.

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As a direct, proximate and legal result of Defendants' negligence, carelessness 93. and other wrongdoing described herein, Plaintiffs have sustained severe injuries as described above.

Based upon information and belief, Defendants actually knew of Ortho Evra's 94. defective nature, as set forth herein, but continued to design, manufacture, market, and sell Ortho Evra to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs in conscious disregard of the foreseeable harm caused by the patch.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as set forth herein below.

Negligent Misrepresentation (Against Defendants ORTHO-MCNEIL and MCKESSON)

- Plaintiffs incorporate by reference the allegations in all preceding paragraphs of 95. this Complaint as though fully set forth in this paragraph.
- 96. Defendants ORTHO-MCNEIL and MCKESSON, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell Ortho Evra, owed a duty to Plaintiffs and the medical community to provide them accurate and complete information regarding this product.
- 97. The Defendants' advertising program, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of Ortho Evra was safe, and had no unacceptable side effects.
- 98. On information and belief, Plaintiffs aver that Defendants failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of Ortho Evra. Defendants deceived potential users and prescribers of the patch by relaying only allegedly positive information, while concealing, misstating and downplaying the known adverse and serious health effects.
- 99. Defendants knew or were aware or should have known or been aware that Ortho Evra had been insufficiently tested and that it lacked necessary warnings. Defendants were or should have been in possession of evidence demonstrating that their product created a high risk

of unreasonable, dangerous side effects, including but not limited to strokes, pulmonary emboli, blood clots, deep vein thrombosis, and heart attacks, as well as other severe permanent health problems. Nonetheless, Defendants continued to market Ortho Evra by providing false and misleading information with regard to its safety and efficacy.

- 100. Plaintiffs and their doctors justifiably relied to their detriment upon Defendants' positive misrepresentations concerning Ortho Evra.
- 101. As a result of Defendants' conduct, Plaintiffs have sustained injuries as described above. Accordingly, Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as set forth herein below.

## SIXTH CAUSE OF ACTION

Fraud

(Against Defendants ORTHO-MCNEIL and MCKESSON)

- 102. Plaintiffs incorporate by reference the allegations in all preceding paragraphs of this Complaint as though fully set forth in this paragraph.
- 103. ORTHO-MCNEIL and MCKESSON, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell Ortho Evra, owed and continue to owe a duty to provide accurate and complete information regarding their product.
- Ortho Evra was just as safe as the oral contraceptives already on the market, and had no unacceptable side effects. by intentionally distributing false information to Plaintiffs, the general public, healthcare professionals and the FDA.
- 105. On information and belief, Plaintiffs aver that the Defendants intentionally concealed, misstated, downplayed, suppressed, and ignored test results that were unfavorable to the Defendants as well as the results that revealed that Ortho Evra was not safe in the prevention of pregnancy. Defendants deceived potential users and prescribers of the patch by disseminating only allegedly positive information while concealing, misstating and downplaying the known adverse and serious health effects. Defendants falsely and deceptively kept relevant information

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from potential Ortho Evra users and minimized safety concerns.

- These representations were made with the purpose of deceiving and defrauding the public, the FDA and the Plaintiffs in order to gain their confidence and falsely ensure the quality and fitness of Ortho Evra.
- In representations made to Plaintiffs, physicians and the public in general, 107. Defendants' fraudulently concealed and intentionally omitted information included, but not limited to the following:
  - A. That Ortho Evra was not as safe as other forms of contraception;
  - That the amount of estrogen Ortho Evra users are exposed to is much В. higher than the levels that oral contraceptive users are exposed to;
  - C. The risk of adverse effects is more likely with Ortho Evra use because of the higher levels of estrogen that the user is exposed to;
  - That even after concerns about serious adverse effects were known, Ortho D. Evra was not adequately tested.
- Defendants were or should have been in possession of evidence demonstrating 108. that their product caused serious side effects. Nevertheless, they continued to market Ortho Evra and represent falsely in their documents that Ortho Evra was safe and did not present any health risks above those associate with the oral contraceptives on the market.
- Defendants knew or should have known that the public, including the Plaintiffs 109. would rely on the information that was being distributed.
- Plaintiffs did in fact rely on and believe Defendants' representations to be true and relied upon the representations, and were induced to purchase and use Ortho Evra. Plaintiffs did not discover the true facts with respect to the dangerous and serious side effects or the false representations that were made by Defendants, nor could the Plaintiffs have discovered the true facts with reasonable diligence.
- Had the Plaintiffs known of the true facts with respect to the dangerous and 111. serious health risks of Ortho Evra, Plaintiffs would not have purchased or used Ortho Evra nor would they have relied on Defendants' false representations.

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- Defendants concealment and omissions of material facts concerning the safety of 112. Ortho Evra was made purposefully, wilfully, wantonly and/or recklessly, to mislead Plaintiffs, and their physicians into continued use and/or dispensing of Ortho Evra.
- Plaintiffs are entitled to punitive damages because the failure of the Defendants to 113. warn was reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the general public, including the Plaintiffs, through false representations about the safety of Ortho Evra.
- The Defendants' actions, as described above, were performed willfully, 114. intentionally, and with reckless disregard for the rights of Plaintiffs and the public.
- Accordingly, Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as set forth herein below.

Document 2-3

Filed 02/08/2008

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## **DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury in this action .

DATED: October 2, 2007

KHORRAMI, POLLARD & ABIR, LLP

y: SHAWN KHORRAMI, ESQ. Attorney for Plaintiff

## NOTICE TO PLAINTIFF

A Case Management Conference is set for

DATE:

MAR-07-2008

TIME:

9:00AM

PLACE:

Department 212

400 McAllister Street

San Francisco, CA 94102-3680

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference.

However, it would facilitate the issuance of a case management order without an appearance at the case management conference if the case management statement is filed, served and lodged in Department 212 twenty-five (25) days before the case management

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state.

## ALTERNATIVE DISPUTE RESOLUTION POLICY REQUIREMENTS

IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE PARTICIPATE IN EITHER MEDIATION, JUDICIAL OR NON-JUDICIAL ARBITRATION, THE EARLY SETTLEMENT PROGRAM OR SOME SUITABLE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A MANDATORY SETTLEMENT CONFERENCE OR TRIAL. (SEE LOCAL RULE 4)

Plaintiff must serve a copy of the Alternative Dispute Resolution Information Package on each defendant along with the complaint. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the Alternative Dispute Resolution Information Package prior to filing the Case Management Statement.

[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]

Superior Court Alternative Dispute Resolution Coordinator 400 McAllister Street, Room 103 San Francisco, CA 94102 (415) 551-3876

See Local Rules 3.6, 6.0 C and 10 D re stipulation to commissioners acting as temporary judges

## Alternative Dispute Resolution (ADR) Information Package

# Alternatives to Trial

# Here are some other ways to resolve a civil dispute.

The plaintiff must serve a copy of the ADR information package on each defendant along with the complaint. (CRC 201.9(c))

Superior Court of California County of San Francisco

## Introduction

Did you know that most civil lawsuits settle without a trial?

And did you know that there are a number of ways to resolve civil disputes without having to sue somebody?

These alternatives to a lawsuit are known as alternative dispute resolutions (ADR). The most common forms of ADR are mediation, arbitration and case evaluation. There are a number of other kinds of ADR as well.

In ADR, trained, impartial persons decide disputes or help parties decide disputes themselves. These persons are called neutrals. For example, in mediation, the neutral is the mediator. Neutrals normally are chosen by the disputing parties or by the court. Neutrals can help parties resolve disputes without having to go to court.

ADR is not new. ADR is available in many communities through dispute resolution programs and private neutrals.

## **Advantages of ADR**

ADR can have a number of advantages over a lawsuit.

- ADR can be speedier. A dispute often can be resolved in a matter of months, even weeks, through ADR, while a lawsuit can take years.
- ADR can save money. Court costs, attorneys fees, and expert fees can be saved.
- ADR can permit more participation. The parties may have more chances to tell their side of the story than in court and may have more control over the outcome.
- ADR can be flexible. The parties can choose the ADR process that is best for them. For example, in mediation the parties may decide how to resolve their dispute.
- ADR can be cooperative. This means that the parties having a dispute may
  work together with the neutral to resolve the dispute and agree to a remedy
  that makes sense to them, rather than work against each other.

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- ADR can reduce stress. There are fewer, if any, court appearances. And because ADR can be speedier, and save money, and because the parties are normally cooperative, ADR is easier on the nerves. The parties don't have a lawsuit hanging over their heads for years.
- ADR can be more satisfying. For all the above reasons, many people have reported a high degree of satisfaction with ADR.

Because of these advantages, many parties choose ADR to resolve a dispute, instead of filing a lawsuit. Even when a lawsuit has been filed, the court can refer the dispute to a neutral before the parties' position harden and the lawsuit becomes costly. ADR has been used to resolve disputes even after a trial, when the result is appealed.

## Disadvantages of ADR

ADR may not be suitable for every dispute.

- If ADR is binding, the parties normally give up most court protections, including a decision by a judge or jury under formal rules of evidence and procedure, and review for legal error by an appellate court.
- There generally is less opportunity to find out about the other side's case with ADR than with litigation. ADR may not be effective if it takes place before the parties have sufficient information to resolve the dispute.
- The neutral may charge a fee for his or her services.
- If a dispute is not resolved through ADR, the parties may have to put time and money into both ADR and a lawsuit.
- Lawsuits must be brought within specified periods of time, known as statutes
  of limitation. Parties must be careful not to let a statute of limitations run out
  while a dispute is in an ADR process.

# ALTERNATIVE DISPUTE RESOLUTION PROGRAMS Of the San Francisco Superior Court

"It is the policy of the Superior Court that every noncriminal, nonjuvenile case participate either in an early settlement conference, mediation, arbitration, early neutral evaluation or some other alternative dispute resolution process prior to a mandatory settlement conference or trial." (Superior Court Local Rule 4)

This guide is designed to assist attorneys, their clients and self-represented litigants in complying with San Francisco Superior Court's alternative dispute resolution ("ADR") policy. Attorneys are encouraged to share this guide with clients. By making informed choices about dispute resolution alternatives, attorneys, their clients and self-represented litigants may achieve a more satisfying resolution of civil disputes.

The San Francisco Superior Court currently offers three ADR programs for civil matters; each program is described below:

- 1) Judicial arbitration
- 2) Mediation
- 3) The Early Settlement Program (ESP) in conjunction with the San Francisco Bar Association.

## JUDICIAL ARBITRATION

## Description

In arbitration, a neutral "arbitrator" presides at a hearing where the parties present evidence through exhibits and testimony. The arbitrator applies the law to the facts of the case and makes an award based upon the merits of the case. When the Court orders a case to arbitration it is called <u>judicial arbitration</u>. The goal of arbitration is to provide parties with an adjudication that is earlier, faster, less formal, and usually less expensive than a trial. Upon stipulation of all parties, other civil matters may be submitted to judicial arbitration.

Although not currently a part of the Court's ADR program, civil disputes may also be resolved through <u>private arbitration</u>. Here, the parties

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voluntarily consent to arbitration. If all parties agree, private arbitration may be binding and the parties give up the right to judicial review of the arbitrator's decision. In private arbitration, the parties select a private arbitrator and are responsible for paying the arbitrator's fees.

## Operation

Pursuant to CCP 1141.11 and Local Rule 4, all civil actions in which the amount in controversy is \$50,000 or less, and no party seeks equitable relief, shall be ordered to arbitration. A case is ordered to arbitration after the Case Management Conference. An arbitrator is chosen from the Court's Arbitration Panel. Most cases ordered to arbitration are also ordered to a pre-arbitration settlement conference. Arbitrations are generally held between 7 and 9 months after a complaint has been filed. Judicial arbitration is not binding unless all parties agree to be bound by the arbitrator's decision. Any party may request a court trial within 30 days after the arbitrator's award has been filed.

#### Cost

There is no cost to the parties for judicial arbitration or for the prearbitration settlement conference.

#### **MEDIATION**

## Description

Mediation is a voluntary, flexible, and confidential process in which a neutral third party "mediator" facilitates negotiations. The goal of mediation is to reach a mutually satisfactory agreement that resolves all or part of the dispute after exploring the significant interests, needs, and priorities of the parties in light of relevant evidence and the law.

Although there are different styles and approaches to mediation, most mediations begin with presentations of each side's view of the case. The mediator's role is to assist the parties in communicating with each other, expressing their interests, understanding the interests of opposing parties, recognizing areas of agreement and generating options for resolution. Through questions, the mediator aids each party in assessing the strengths and weaknesses of their position.

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A mediator does not propose a judgment or provide an evaluation of the merits and value of the case. Many attorneys and litigants find that mediation's emphasis on cooperative dispute resolution produces more satisfactory and enduring resolutions. Mediation's non-adversarial approach is particularly effective in disputes in which the parties have a continuing relationship, where there are multiple parties, where equitable relief is sought, or where strong personal feelings exist.

## Operation

San Francisco Superior Court Local Court Rule 4 provides three different voluntary mediation programs for civil disputes. An appropriate program is available for all civil cases, regardless of the type of action or type of relief sought.

To help litigants and attorneys identify qualified mediators, the Superior Court maintains a list of mediation providers whose training and experience have been reviewed and approved by the Court. The list of court approved mediation providers can be found at www.sfgov.org/courts. Litigants are not limited to mediators on the court list and may select any mediator agreed upon by all parties. A mediation provider need not be an attorney.

Local Rule 4.2 D allows for mediation in lieu of judicial arbitration, so long as the parties file a stipulation to mediate within 240 days from the date the complaint is filed. If settlement is not reached through mediation, a case proceeds to trial as scheduled.

### Private Mediation

The Private Mediation program accommodates cases that wish to participate in private mediation to fulfill the court's alternative dispute resolution requirement. The parties select a mediator, panel of mediators or mediation program of their choice to conduct the mediation. The cost of mediation is borne by the parties equally unless the parties agree otherwise.

Parties in civil cases that have not been ordered to arbitration may consent to private mediation at any point before trial. Parties willing to submit a matter to private mediation should indicate this preference on the Stipulation to Alternative Dispute Resolution form or the Case Management Statement (CM-110). Both forms are attached to this packet.

# Mediation Services of the Bar Association of San Francisco

Case 3:08-cv-00862-SC

The Mediation Services is a coordinated effort of the San Francisco Superior Court and The Bar Association of San Francisco (BASF) in which a court approved mediator provides three hours of mediation at no charge to the parties. It is designed to afford civil litigants the opportunity to engage in early mediation of a case shortly after filing the complaint, in an effort to resolve the matter before substantial funds are expended on the litigation process. Although the goal of the program is to provide the service at the outset of the litigation, the program may be utilized at anytime throughout the litigation process.

The mediators participating in the program have been pre-approved by the court pursuant to strict educational and experience requirements.

After the filing of the signed Stipulation to Alternative Dispute Resolution form included in this ADR package the parties will be contacted by BASF. Upon payment of the \$200 per party administration fee, parties select a specific mediator from the list of court approved mediation providers. The hourly mediator fee beyond the first three hours will vary depending on the mediator selected. Waiver of the administrative fee based on financial hardship is available.

A copy of the Mediation Services rules can be found on the BASF website at <a href="https://www.sfbar.org">www.sfbar.org</a>, or you may call BASF at 415-782-8913

### Judicial Mediation

The Judicial Mediation program is designed to provide early mediation of complex cases by volunteer judges of the San Francisco Superior Court. Cases considered for the program include construction defect, employment discrimination, professional malpractice, insurance coverage, toxic torts and industrial accidents.

Parties interested in judicial mediation should file the Stipulation to Alternative Dispute Resolution form attached to this packet indicating a joint request for inclusion in the program. A preference for a specific judge may be indicated. The court Alternative Dispute Resolution Coordinator will coordinate assignment of cases that qualify for the program.

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#### Cost

Generally, the cost of Private Mediation ranges from \$200 per hour to \$400 per hour and is shared equally by the parties. Many mediators are willing to adjust their fees depending upon the income and resources of the parties. Any party who meets certain eligibility requirements may ask the court to appoint a mediator to serve at no cost to the parties.

The Mediation Services of the Bar Association of San Francisco provides three hours of mediation time at no cost with a \$200 per party administrative fee.

There is no charge for participation in the Judicial Mediation program.

## **EARLY SETTLEMENT PROGRAM**

### Description

The Bar Association of San Francisco, in cooperation with the Court, offers an Early Settlement Program ("ESP") as part of the Court's settlement conference calendar. The goal of early settlement is to provide participants an opportunity to reach a mutually acceptable settlement that resolves all or part of the dispute. The two-member volunteer attorney panel reflects a balance between plaintiff and defense attorneys with at least 10 years of trial experience.

As in mediation, there is no set format for the settlement conference. A conference typically begins with a brief meeting with all parties and counsel, in which each is given an opportunity to make an initial statement. The panelists then assist the parties in understanding and candidly discussing the strengths and weaknesses of the case. The Early Settlement Conference is considered a "quasi-judicial" proceeding and, therefore, is not entitled to the statutory confidentiality protections afforded to mediation.

## Operation

Civil cases enter the ESP either voluntarily or through assignment by the Court. Parties who wish to choose the early settlement process should indicate this preference on the status and setting conference statement.

If a matter is assigned to the ESP by the Court, parties may consult the ESP program materials accompanying the "Notice of the Early Settlement Conference" for information regarding removal from the program.

Participants are notified of their ESP conference date approximately 4 months prior to trial. The settlement conference is typically held 2 to 3 months prior to the trial date. The Bar Association's ESP Coordinator informs the participants of names of the panel members and location of the settlement conference approximately 2 weeks prior to the conference date.

Local Rule 4.3 sets out the requirements of the ESP. All parties to a case assigned to the ESP are required to submit a settlement conference statement prior to the conference. All parties, attorneys who will try the case, and insurance representatives with settlement authority are required to attend the settlement conference. If settlement is not reached through the conference, the case proceeds to trial as scheduled.

#### Cost

All parties must submit a \$200 generally non-refundable administrative fee to the Bar Association of San Francisco. Parties who meet certain eligibility requirements may request a fee waiver. For more information, please contact the ESP Coordinator at (415) 982-1600.

For further information about San Francisco Superior Court ADR programs or dispute resolution alternatives, please contact:

Superior Court Alternative Dispute Resolution Coordinator, 400 McAllister Street, Room 103 San Francisco, CA 94102 (415) 551-3876

or visit the Superior Court Website at http://sfgov.org/site/courts\_page.asp?id=3672

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# SUPERIOR COURT OF CALIFORNIA COUNTY OF SAN FRANCISCO

400 McAllister Street, San Francisco, CA 94102-4514

	Plaintiff	Case	No
·		STIP DISP	ULATION TO ALTERNATIVE UTE RESOLUTION
	Defendant		I
The parties hereby st resolution process:	ipulate that this action shall be	submitted to the follo	wing alternative dispute
L BASE Early Se		on Services of BASF	☐ Judicial Mediation Judge Judge
Plaintiff(s) and Defend	ant(s) further agree as follows:		
Name of Party Stipulating	Name of Party or Attorney Exe	cuting Stipulation Signature	gnature of Party or Attorney
☐ Plaintiff ☐ Defendant [	☐ Cross-defendant	•	The day of Attorney
Name of Party Stipulating	Name of Party or Attorney Exec	uting Stipulation Sig	nature of Party or Attorney
☐ Plaintiff ☐ Defendant ☐	] Cross-defendant	Dated:	
Name of Party Stipulating	Name of Party or Attorney Exec	Iting Stinutation Sign	Software of Day
☐ Plaintiff ☐ Defendant ☐		Dated:	nature of Party or Attorney
Additional signature(s) attache	d		
ACD A Man			

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and	CM
address).	FOR COURT USE GNLY
TELEPHONE NO: FAX NO. (Optional):	
E-MAIL ADDRESS (Optional):	
ATTORNEY FOR (Name):	
SUPERIOR COURT OF CALIFORNIA, COUNTY OF	<b></b>
STREET ADDRESS:	
MAILING ADDRESS:	
CITY AND ZIP CODE:	
BRANCH NAME:	
PLAINTIFF/PETITIONER:	
DEFENDANT/RESPONDENT:	
CACE BRANKS CONTROL OF THE CONTROL O	
CASE MANAGEMENT STATEMENT	CASE NUMBER:
(Check one): UNLIMITED CASE LIMITED CASE	
(Amount demanded exceeds \$25,000) (Amount demanded is \$25,000) (Amount demanded is \$25,000)	0
exceeds \$25,000) or less)	
A CASE MANAGEMENT CONFERENCE is scheduled as follows:	
Dafe: Time: Dept.:	Div.: Room:
Address of court (if different from the address above):	r com.
INSTRUCTIONS: All applicable boxes must be checked, and the specific	ed information must be provided.
Party or parties (answer one);	
a This statement is submitted by party (name): b This statement is submitted jointly by parties (names):	
or this statement is submitted jointly by parties (names):	
Complaint and cross-complaint (to be answered by plaintiffs and cross-complainer	
a. The complaint was filed on (date):	nts only)
b. The cross-complaint, if any, was filed on (date):	
Service (to be answered by plaintiffs and cross-complainants only)	
a. All parties named in the complaint and cross-complaint have been served.	Of have appeared or have been dismissed
b. The following parties named in the complaint or cross-complaint	, or make depended, of make been dismissed.
(1) have not been served (specify names and explain why not):	
topown) named and explain way holy.	
(2) have been served but have not appeared and have not been	dismissed (equality and
	usinisseu (specify names):
(3) have had a default entered against them (specify names):	
c. The following additional parties may be added (specify names, nature of in they may be served):	volvement in once and the set to the
they may be served):	reservation in case, and the date by which
Description of case	
a. Type of case in complaint cross-complaint (describe, inc	cluding causes of action):

Form Adopted for Mandatory Use Judicial Council of California CM-110 [Rev. January 1, 2007]

Page 1 of 4 Car Rules of Court, rules 3,720-3,730 answ coudinto ca.gov 

PLAINTIFF/PETITIONER:		CM-
DEFENDANT/RESPONDENT:	CASE NUMBER:	
DET CHOMMINESPONDENT:		
<ol> <li>b. Provide a brief statement of the case, including any damages. (If personal damages claimed, including medical expenses to date [indicate source are earnings to date, and estimated future lost earnings. If equitable relief is sometimes.)</li> </ol>	ol injury damages are sought, specify the nd amount], estimated future medical exp sought, describe the nature of the relief.)	e injury an penses, los
	•	
(If more space is needed, check this box and attach a page designated	as Attachment 4b.)	
5. Jury or nonjury trial		*
The party or parties request a jury trial a populary trial	Toro than ano north annual to	·
requesting a jury trial):	nore than one party, provide the name of	each party
•		
. Trial date		•
<ul> <li>a The trial has been set for (date):</li> <li>b No trial date has been set. This case will be ready for trial within 12 mot, explain):</li> </ul>	nonths of the date of the filing of the com	plaint (if
C. Dates on which parties or attornove with math	•	-
c. Dates on which parties or attorneys will not be available for trial (specify dat	es and explain reasons for unavailability	<b>)</b> :
Estimated length of trial		
The party or parties estimate that the trial will take (check one):		
a. Ladays (specify number).		•
b. hours (short causes) (specify):		
Trial representation to be appropriate		
Trial representation (to be answered for each party)  The party or parties will be represented at trial by the attorney or party lie		
a. Attorney:	sted in the caption by the following	úā:
b. Firm:		•
c. Address: d. Telephone number		
d. Telephone number: e. Fax number:		
f. E-mail address:		
g. Party represented:		
Additional representation is described in Attachment 8.		
Preference		•
This case is entitled to preference (specify code section):		. :
Alternative Dispute Resolution (ADR)	•	
a. Counsel has has not provided the ADR information provided	ge identified in rule 3.221 to the client and	-t
		1 has
b. All parties have agreed to a form of ADR. ADR will be completed by (date	9);	
c. The case has gone to an ADR process (indicate status);		
The second secon		

	PLAINTIFF/PETITIONER:	CM-11
	<u>!</u>	CASE NUMBER:
	DEFENDANT/RESPONDENT:	
	10. d. The party or parties are willing to participate in (check all that apply):	
	(1) Mediation (2) Nonbinding judicial arbitration under Code of Child Sun and Sun an	· · · · · · · · · · · · · · · · · · ·
	(2) Nonbinding judicial arbitration under Code of Civil Procedure section 1 arbitration under Cal. Rules of Court, rule 3.822)	141.12 (discovery to close 15 days before
	(3) Nonbinding judicial arbitration under Code of Civil Procedure section 1	141 12 /discovorus a same
	The state of the s	141112 (discovery to remain open until 30 day
	(4) Binding judicial arbitration (5) Binding private arbitration	
	(6) Neutral case evaluation	
	(7) Other (specify):	
	e This matter is subject to mandatony indicial arbitration (	
1.	to be a support to instructory judicial arbitration because the amount in	controversy does not exceed the statutory li
	f. Plaintiff elects to refer this case to judicial arbitration and agrees to limit recover Procedure section 1141.11.	
	g This case is exempt from judicial arbitration under rule 3.811 of the California	Rules of Court (specify exemption)
		ter territy exampled by
1	1. Settlement conference	
	The party or parties are willing to participate in an early settlement conference (sp	ecify when):
12	2. Insurance	·
	a. Insurance carrier, if any, for party filing this statement (name):	
	b Reservation of rights: Yes No	
	c. Coverage issues will significantly affect resolution of this case (explain).	
13,	Jurisdiction	
	Indicate any matters that may affect the court's jurisdiction or processing of this case, and Bankruptcy Other (specify):	d describe the status.
	Status:	
14	Related cases, consolidation, and coordination	
	a There are companion, underlying, or related cases.	
	(1) Name of case:	
	(2) Name of court: (3) Case number:	
	(4) Status;	
	Additional cases are described in Attachment 14a.	
1	b. A motion to consolidate coordinate will be filed by (nar	me nerty)
5 F	Bifurcation	
	The party or parties intend to file a motion for an order bifurcating, severing, or coord action (specify moving party, type of motion, and reasons):	inating the following issues or causes of
3. C	Other motions	
_	The party or parties expect to file the following motions before trial (specify moving pa	arty, type of motion, and iscuser-
		and addital.
-		

PLAINTIFF/PETITIONER:		CN
		CASE NUMBER:
DEFENDANT/RESPONDENT:		
17. Discovery a. The narty or parties have completed all the		
- Party of parties have completed all discover	ry.	
the residential discovery will be completed by the	e date specified (describe al	f anticipated discovery):
<u>Party</u> <u>Descri</u>		<u>Date</u>
		·.
c. The following discovery issues are anticipated (s	necify):	
100		
40 5		
18. Economic Litigation  a. This is a limited civil case (i.e., the amount demar of Civil Procedure sections 90 through 98 will app	nded is \$25,000 or less) and	the economic litigation procedures in Coo
b. This is a limited civil case and a matter and a		
discovery will be filed (if checked, explain specific should not apply to this case):	ally why economic litigation	nic litigation procedures or for additional procedures relating to discovery or trial
	,	
19. Other issues		
The party or parties request that the following addition conference (specify):	al matters be considered or	determined at the case management
00 14		
20. Meet and confer	•	÷
<ul> <li>The party or parties have met and conferred with a of Court (if not, explain):</li> </ul>	ll parties on all subjects requ	ired by rule 3.724 of the California Rules
	. •	
<ul> <li>After meeting and conferring as required by rule 3.724 of (specify):</li> </ul>	the Callengton D. J.	
(specify);	the California Rules of Cou	rt, the parties agree on the following
24 . 0		
21. Case management orders  Previous case management orders in this area.		* *
Previous case management orders in this case are (check on	e): none at	tached as Attachment 21.
22. Total number of pages attached (if any):		
am completely familiar with this case and will be fully prepared to aised by this statement, and will possess the authority to enter into onference, including the written authority of the party where require	discuss the status of discov	ery and ADR, as well as other issues
onference, including the written authority of the party where require	o sipulations on these issue réd.	is at the time of the case management
ate.		
(TYPE OR PRINT NAME)		
	(S/GNA	TURE OF PARTY OR ATTORNEY)
		•
(TYPE OR PRINT NAME)	(SIGN	ATURE OF PARTY OR ATTORNEY)
	Additional signa	itures are attached
-110 [Rev. January 1, 2007]		•



# Superior Court of California County of San Francisco

# Judicial Mediation Program

Introducing a new court alternative dispute resolution program that provides judicial mediation of complex civil cases

The Judicial Mediation program offers mediation of complex civil litigation by a San Francisco Superior Court judge familiar with the area of the law that is the subject of the controversy. Cases that will be considered for participation in the program include, but are not limited to professional malpractice, construction, employment, insurance coverage disputes, mass torts and complex commercial litigation. Judicial mediation offers civil litigants the opportunity to engage in early mediation of a case shortly after filing the complaint in an effort to resolve the matter before substantial funds are expended. This program may also be utilized at anytime throughout the litigation process. The panel of judges currently participating in the program includes:

The Honorable David L. Ballati The Honorable Anne Bouliane The Honorable Ellen Chaitin The Honorable John J. Conway The Honorable Robert L. Dondero The Honorable Ernest H. Goldsmith The Honorable Curtis E. A. Karnow The Honorable Patrick J. Mahoney

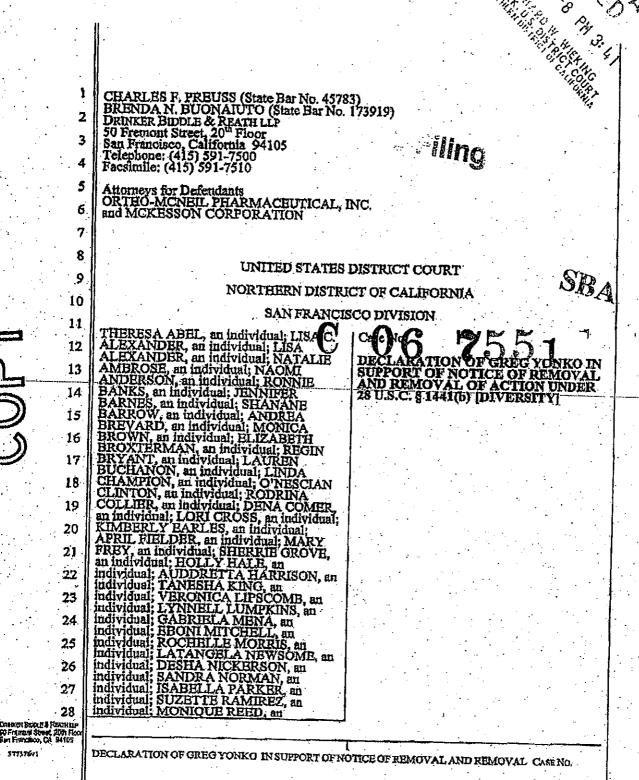
The Honorable Tomar Mason The Honorable James J. McBride The Honorable Kevin M. McCarthy The Honorable John E. Munter The Honorable Ronald Evans Quidachay The Honorable A. James Robertson, II The Honorable Mary E. Wiss

Parties interested in judicial mediation should file the Stipulation to Alternative Dispute Resolution form attached to this packet indicating a joint request for inclusion in the program and deliver a courtesy copy to Dept. 212. A preference for a specific judge may be indicated. The court Alternative Dispute Resolution Coordinator will facilitate assignment of cases that qualify for the program.

Note: Space is limited. Submission of a stipulation to judicial mediation does not guarantee inclusion in the program. You will receive written notification from the court as to the outcome of your application.

> Superior Court Alternative Dispute Resolution 400 McAllister Street, Room 103, San Francisco, CA 94102 (415) 551-3876

**EXHIBIT B** 



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Individual; GENEVIEVE RENFRO, an individual; JENNIFER ROUSE, an individual; ELIZABETH SMITH, an individual; TJUANA STEWART-MARK, an individual; LATOSHA UNDERWOOD, an individual; COSONDA WHAVER, an individual; SAMANTHA WINCHESTER, an individual;

#### Plaintiffs.

V.

ORTHO-MCNEIL PHARMACEUTICAL, INC., a Delaware Corporation; MCKESSON CORP. and DOES 1-500, inclusive,

#### Defendants.

#### I, GREG YONKO, declare:

- 1. I am Senior Vice President Purchasing for McKesson Corporation ("McKesson"). I make this Declaration based on my personal knowledge and/or information assembled by employees of McKesson, which I am informed and believe to be true. I would and could competently testify to the matters stated in this Declaration if called as a witness.
- 2. McKesson was and is a Delaware corporation, with its principal place of business in San Francisco, California.
- McKesson was served with the Summons and Complaint in this action on November 15, 2006.
  - 4. McKesson consents to the removal of this action.
- 5. McKesson had no involvement in the development or preparation of the prescribing information for Ortho Evra® and did not have any responsibility for the content of other written warnings concerning Ortho Evra®.
- 6. At no time has McKesson had any involvement with the manufacture, development, or testing of Ortho Evra®,
  - At no time has McKesson had any involvement with the packaging,

COMMUNICATION E REACTION FINE TO PRODUCE SMARL 2010 FINE Box Projectico, CA 191105

DECLARATION OF GREG YORKO IN SUPPORT OF NOTICE OF REMOVAL AND REMOVAL CASE NO.

labeling, advertising, promotion, or marketing of Ortho Evra®.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 2006, in San Francisco,

GREG YONKO

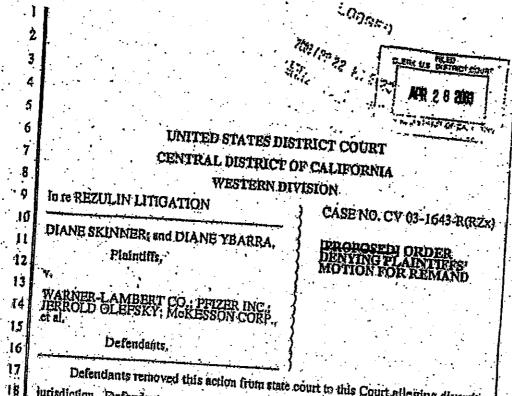
DECLARATION OF GREG YORKO IN SUPPORT OF NOTICE OF REMOVAL AND REMOVAL CASE NO.

**EXHIBIT C** 

jurisdiction. The Court further finds that there is no possibility that plaintiffs could prove a cause of action against McKesson, an entity which distributed this PDA-approved 3 medication to pharmacists in California. Pursuant to continent k of the Restatement 4 (Second) of Tures Section 402A and California law following comment k, a 5 distributor of a prescription drug is not subject to strict liability. 6 Accordingly, this Court has diversity jurisdiction over each of these actions. 8 The motion to remaind is detiled, 9 IT IS SO ORDERED. Dated: April 28, 2003 10 IJ MANUEL L. REAL 12 MANUELL REAL UNITED STATES DISTRICT JUDGE 13 Submitted by: O'DONNELL & SHAEFFER LLP 033 West Fifth Street, Suite 1700 Los Angeles, California 90071 Letephone: (213) 532-2000 Facsimile: (213) 532-2020 17 KAYE SCHOLER LLP 1999 Avenue of the Stars Los Angeles, Callfornia 9006 Telephone: (310) 788-1000 Facsibile: (310) 788-1200 18 19 20 By: Court Barries 21 Attorneys for Defendants
WARNER-LAMBERT COMPANY and PRIZER INC. 22 23 24 25 26 27 28

"

# **EXHIBIT D**



Defendants removed this action from state court to this Court efleging diversity jurisdiction. Defendants asserted that Jerrold Olefsky and McKesson Corp., both of whom are California residents, were fraudulently joined. Plaintiffs moved to remand to state court. The motions came on for hearing by the Court on April 21, 2003.

Having considered fite motions and other documents in support of and in opposition to the motions, having heard the arguments of counsel, and being fully advised in the matter, the Court deales the motion.

The Court finds that Dr. Jerrold Olefsky ("Dr. Olefsky"), a patent-holder and clinical investigator, owed no legal duty to any of the plaintiffs, and, therefore, there is no possibility that the plaintiffs can prove a cause of action against Dr. Olefsky. Thus, Dr. Olefsky must be disregarded for purposes of determining federal diversity jurisdiction.

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KAYE SCHOLERUP

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PROPOSEDI DEDE

The Court further finds that there is no possibility that plaintiffs could prove a cause of action against McKesson, an entity which distributed this FDA-approved 2 medication to pharmacists in California. Pursuant to comment k of the Restalement 3 (Second) of Tons Section 402A and California law following comment k, a 4 distributor of a prescription drug is not subject to strict liability. Accordingly, this Court has diversity jurisdiction over each of these actions. The motion to remand is denied. IT IS SO ORDERED. Dated: April 28, 2003 MANUEL L. REAL Submitted by: 13 D'DONNELL & SHAEFFE 33 West Fifth Street, Suite os Angeles, Callfornia 900 elephone: (213) 532-2000 ecsimile: (213) 532-2020 15 16 18 By: Robert Barries

Robert Barries

Anomeys for Describants

WARNER-LAMBERT COMPANY and PFIZER INC 19 20 21 22 23 24 25 25 27 28 Diditar web